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EDWARDS ANGELL PALMER & DODGE LLP			QAZI, SABIHA NAIM	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,164	COLLI, ENRICO	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 August 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-4, 7-9, 13 and 15-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-4, 7-9, 13 and 15-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

Non-Final Office Action

Claims 2-4, 7-9, 13 and 15-31 are pending. No claim is allowed at this time.

Amendments are entered.

Summary of the Office Action Tuesday dated August 27, 2009

1. Continued Examination under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 112 (1) Written Description and New Matter Rejection
6. 35 USC § 103(a) Obviousness Rejection – First Rejection
7. 35 USC § 103(a) Obviousness Rejection – Second Rejection
8. Response to Remarks and Declaration
9. Communication

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2009 has been entered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112—Written Description Rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4, 9, 13 and 15-31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.

New Matter

The disclaimer in claim 2 is considered "new matter".

- MPEP 2173.05(i) states: "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. Only if alternative elements are positively recited in the specification, they may be

explicitly excluded in the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification, they are generically disclosed, so the Applicants argument is not relevant to the current issues.

- In the present case compounds were generically disclosed. After the rejection Applicants have disclaimed the specific compounds, which were taught by the prior art.
- See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). Any claim containing a negative limitation, which does not have basis in the original disclosure, should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.
- The instant claim 2 therefore is rejected under 35 U.S.C. 112, first paragraph, under instruction from MPEP 2173.05(i), because it contain a negative limitation that has no basis in the original disclosure.

- In *Purdue Pharma LP v Faulding, Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000), the court noted that with respect to *In re Ruschig*, 371 F.2d 990, 154 USPQ 118 (CCPA 1967), “Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick out a tree of the forest and say, “here is my invention”. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”
- *Purdue* is relevant in this case, because the Appellants disclosed a genus (“a forest”) in the original application, then later picked out two specific compounds (“a tree of the forest”), and are now saying, “here is my invention”. In order to satisfy the written description requirement, according to *Purdue*, the Appellants must disclose the specific compounds in the originally filed disclosure.” (See (56 USPQ2D 1481).
- More from *Purdue*: The case of *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), is instructive here (see page 1487). The claim at issue in that case was directed to a single compound. The appellants argued that, although the compound itself was not

disclosed, one skilled in the art would find support for the claimed compound in the general disclosure of the genus of compounds to which the claimed compound belonged. The Ruschig court rejected that argument, stating: [i]t is an old custom in the woods to mark trails by making blaze marks on the trees. It is of no help in finding a trail or in finding one's way through the woods where the trails have disappeared-or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. We are looking for blaze marks, which single out particular trees. We see none. *Id.* at 994-95, 154 USPQ at 122.

Written Description

There is no teaching or guidance how “prevention” of bladder dysfunction by such a large number of compounds would be treated successfully. It appears that Applicant s have no possession of claimed subject matter at the time the invention was filed.. Applicant is kindly requested to show that at the time of invention Applicants were in possession of the claimed invention.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or

specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

See MPEP 2163.06.

Double Patenting Rejection

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4, 9, 13 and 15-31 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 9, 11, 12, 15, 23, 24, 31 and 32 of Application No. 10/903,211 (recently allowed).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of "211 are drawn to a method for treating benign prostatic hyperplasia in a Patient in need of such treatment comprising administering to said patient a therapeutically effective amount of 1 -alpha-fluoro-25-hydroxy-16,23E-diene-26,27-bishomo-20-epi- cholecalciferol or a pharmaceutically acceptable salt or ester thereof. Claims of the present invention are drawn to a method of prevention or treatment of bladder dysfunction in a patient by administering to a patient in need thereof an effective amount of vitamin D compound thereby to prevent or treat bladder dysfunction in said patient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: Following reasons apply: Claim 3 is drawn to a method according to claim 2 which further comprises the step of obtaining or synthesizing the Vitamin D compound.

There are no steps for synthesizing or method for obtaining vitamin D compounds. Claims are open ended.

Claim Rejections - 35 USC § 103---1st Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 9, 13 and 15-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over BATCHO et al. United States Patent No. 5,939, 408, BISHOP et al. WO 98/29123 and BISHOP et al. (US Patent 6,566,353). These references teach vitamin D compounds useful for the treating benign prostatic hyperplasia (BPH), which embraces Applicant's claimed invention.

BATCHO teaches 1 --flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-cholecalciferol. See the entire document especially summary of invention in column 1 where R represents F, R₂ represents alkyl and X represents =CH₂, lines 55-65 in column 2, **example 38** (col. 34) and claim 26 which is drawn to a method for treating neoplastic disease. These compounds induce cell differentiation and inhibition of proliferation in various cancer cell lines. Various other uses are disclosed.

BISHOP WO '123 teaches method and composition of treating prostatic disease using active vitamin D compounds. The invention provides a method of treating prostatic disease conditions such as those characterized by hyperproliferative cell growth and/or abnormal cell differentiation, e.g. prostate cancer and prostate hyperplasia. See the entire document especially, lines 1-10 on page 5. Furthermore, reference teaches addition of active agents such as 5a-reductase enzyme inhibitor such as finasteride, flutamide etc. See lines 26-31 on page 13.

BISHOP US '353 teaches a method of treating hypercalcemia associated with malignant or neoplastic cells, comprising the cells with an effective amount of a vitamin D compound having a hydrocarbon moiety at C-24 position, where the cells are cancers of the bladder (see claim 1 and 2). See the entire document especially lines 52-67 in column 2, lines 1-65 in column 3, examples and claims

Instant claims are taught by all the references cited above.

It would have been obvious to one skilled in the art at the time of invention was made to use the 1 --flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-cholecalciferol for treating prostate hyperplasia because BISHOP references teaches method of treating prostate hyperplasia by vitamin D compounds. The motivation to select this particular compound R0-26-9228 is because one would expect vitamin D compounds to inhibit prostate hyperplasia because BISHOP teaches the same use. The combination of various active agents is also taught by the prior art such as 5a-reductase enzyme inhibitor, finasteride, flutamide. BISHOP further teaches a method of treating hypercalcemia associated with malignant or neoplastic cells, comprising the cells with an effective amount of a vitamin D compound having a hydrocarbon moiety at C-24 position, where the

cells are cancers of the bladder. Since instant claims are drawn to “bladder dysfunction” it includes every disease which is caused by bladder dysfunction.

The invention as presently claimed appears to be a routine experimentation of the teachings of prior art at the time of invention. See KSR Supreme Court of United States Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC. et al. No. 04-1350) where it states that (1) “However, the issue is not whether a person skilled in the art had the motivation to combine the electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach the electronic control to the support bracket of pedal assembly”. (2) "the results of ordinary innovation are not the subject of exclusive rights under the patent laws". In the present case the method as claimed would have been obvious to one skilled in the art at the time the invention was made.

In the light of the forgoing discussion, the Examiner’s ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a)¹.

Claim Rejections - 35 USC § 103---2nd Rejection

Claims 2-4, 9, 13 and 15-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over BATCHO et al. United States Patent No. 5,939, 408, in view of CRESCIOLI et al. (J. of Clinical Endocrinology & Metabolism). These references teach vitamin D compounds useful for the treating benign prostatic hyperplasia (BPH), which embraces Applicant's claimed invention.

BATCHO teaches 1 --flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-calciferol. See the entire document especially summary of invention in column 1 where R represents F, R₂ represents alkyl and X represents =CH₂, lines 55-65 in column 2, **example 38** (col. 34) and claim 26 which is drawn to a method for treating neoplastic disease. These compounds induce cell differentiation and inhibition of proliferation in various cancer cell lines. Various other uses are disclosed.

BATCHO does not teach specifically the treatment of prostate hyperplasia (it teaches the treatment of neoplastic disease by the same compound as presently claimed. (See claim 26 and example 38 in col. 34).

¹ Examiner notes, that SERIO ET AL. FR 97/A/000269 teaches vitamin D compound RO 23-7553 which is 1, 25-

CRESCIOLI et al. teaches 1alpha--25-dihydroxy-16, 23E-diene-D3 (analog V). The reference discloses the effect of vitamin D and its analog (V) on basal and KGF-induced proliferation and apoptosis in BPH cells. See results and fig. 2 on page 2579.

Instant claims differ from the reference in claiming method of prevention and/or treatment using specific compound 1alpha-flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-cholecalciferol.

It would have been obvious to one skilled in the art at the time of invention was made to use the 1alpha--flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-calciferol for treating prostate hyperplasia because BATCHO teaches 1alpha--flouro-25-hydroxy-16, 23E-diene-26, 27-bishomo-20-epi-calciferol as presently for the treatment of neoplastic disease and CRESCIOLI teaches the non hypercalcemic analogue of vitamin D analog decreases growth factor induced human BPH cell proliferation and survival. The motivation to select compound R0-26-9228 as claimed because one would expect vitamin D compounds to inhibit prostate hyperplasia because CRESCIOLI teaches the same use.

Furthermore, the combination of various active agents is also taught by the prior art such as 5a-reductase enzyme inhibitor, finasteride, flutamide.

The invention as presently claimed appears to be a routine experimentation of the teachings of prior art at the time of invention. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a)²..

Response to Remarks

Applicants' arguments, filed on 7/24/09 have been fully considered.
Rejections and/or objections not reiterated from previous office actions are hereby

claims 1 and 7, Fig. 1 and 2.

² Examiner notes, that SERIO ET AL. FR 97/A/000269 teaches vitamin D compound RO 23-7553 which is 1, 25-dihydroxy-16, 23-yno vitamin D3 for the treatment of BPH, see last two paragraphs on page 7, claims especially claims 1 and 7, Fig. 1 and 2.

withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's argument and interpretation for *In re Johnson* was not found persuasive. MPEP 2173.05(i) states: "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. Only if alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification, they are generically disclosed, so the Applicants argument is not relevant to the current issues.

- In the present case compounds were generically disclosed. After the rejection Applicants have disclaimed the specific compounds, which were taught by the prior art.
- Rejection under 112 (2) is maintained because the amendments do not overcome the rejection. Applicant argues and refers to other

published references where the steps are not described. Applicant is requested to write the basic steps for making the compounds.

- Applicants elected species of the compound 1-alpha-fluoro-25-hydroxy-16, 23E-diene-26, 27- bishomo-20-epi-cholecalciferol, which is disclosed in claim 19. The claims readable on the elected species include claims 2-4, and 9, 13 and 15-19.
- The declaration filed by Applicant was fully considered but was not found persuasive in view of amended claims. The data presented is not for prevention of active bladder as has been claimed. Applicant has distinguished the differences between "overactive bladder" and BPH. In a situation when according to Applicant prior art does not teach or suggest the method, more data and/guidance is required to make and use the invention. In any case Applicant has no possession for "preventing" the overactive bladder.
- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571)

272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612

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